



EESTI STANDARDI EESSÕNA NATIONAL FOREWORD

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EUROPEAN STANDARD

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English version odstuffs - Methods of analysis for the detection of genetically modified organisms and derived products - Nucleic acid extraction (ISO 21571:2005) Produits alimentaires - Méthodes d'analyse pour la détection des organismes génétiquement modifiés et des produits dérivés - Extraction des acides nucléiques (ISO Lebensmittel - Verfahren zum Nachweis von gentechnisch modifizierten Organismen und irhen Produkten -Nukleinsäureextraktion (ISO 21571:2005) 21571:2005) This European Standard was approved by CEN on 14 February 2005. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member. This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions. CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom. Ocheratio of the other EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 21571:2005 (E)



This document (EN ISO 21571:2005) has been prepared by Technical Committee CEN/TC 275 "Food analysis - Horizontal methods", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 34 "Agricultural food products".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2005, and conflicting national standards shall be withdrawn at the latest by August 2005

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, internet internet of the second secon Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

INTERNATIONAL STANDARD



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Foodstuffs — Men. the detection of genen. organisms and derived Nucleic acid extraction Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products -

Produits alimentaires — Méthodes d'analyse pour la détection des organismes génétiquement modifiés et des produits dérivés —

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

ISO 21571 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 275, *Food analysis* — *Horizontal methods*, in collaboration with Technical Committee ISO/TC 34, *Food products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

The search for genetically modified origin of ingredients is performed by means of the following successive (or simultaneous) steps. After sample collection, nucleic acids are extracted from the test portion. Extracted nucleic acids can be further purified, simultaneously or after the extraction process. Afterwards, they are quantified (if necessary), diluted (if necessary) and subjected to analytical procedures (such as PCR). These steps are detailed in this and the following International Standards:

ISO 21568, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Sampling.

ISO 21569, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Qualitative nucleic acid based methods.

ISO 21570, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Quantitative nucleic acid based methods.

Further information about definitions and general items involving the steps cited above are collected in:

ISO 24276, Foodstuffs — Nucleic acid based methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions.

The International Organization for Standardization (ISO) draws attention to the fact that it is claimed that compliance with this document may involve the use of a patent concerning the silica-based extraction method (No. EP 0389063/USP 5,234,809) given in Clause A.4.

ISO takes no position concerning the evidence, validity and scope of this patent right.

The holder of this patent right has assured the ISO that he/she is willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statement of the holder of this patent right is registered with ISO. Information may be obtained from:

Jean Deleforge, BioMérieux Chemin de l'Orme, 69280 Marcy-l'Étoile, France.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those identified above. ISO shall not be held responsible for identifying any or all such patent rights.

Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Nucleic acid extraction

1 Scope

This International Standard provides general requirements and specific methods for DNA extraction/purification and quantitation. These methods are described in Annexes A and B.

This International Standard has been established for food matrices, but could also be applicable to other matrices, such as grains and feed.

It has been designed as an integral part of nucleic-acid-based analytical methods, in particular ISO 21569 on qualitative analytical methods, and ISO 21570 on quantitative analytical methods.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 24276:—¹⁾, Foodstuffs — Nucleic acid based methods of analysis for the detection of genetically modified organisms and derived products — General requirements and definitions

ISO 21568, Foodstuffs — Methods of analysis for the detection of genetically modified organisms and derived products — Sampling

3 Principle

3.1 General

The objective of nucleic acid extraction methods is to provide nucleic acids suitable for subsequent analysis (see ISO 24276).

NOTE The "quality" of DNA depends on the average length of the extracted DNA molecules, the chemical purity and the structural integrity of the DNA sequence and of the double helix (e.g. intra-, inter-strand linking between DNA bases, single-strand gaps, cross-linking with polyols, haemin, etc). Moreover, such alterations are often sequence-specific and consequently not randomly distributed all over the genome (see References [1], [2], [3] and [4]).

Users of this International Standard should note that some methods (e.g. all silica-based methods), might be covered by patent rights.

1) To be published.